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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/803,126	03/17/2004	James Robert Schwartz	9183M&	4865

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THE PROCTER & GAMBLE COMPANY  
Global Legal Department - IP  
Sycamore Building - 4th Floor  
299 East Sixth Street  
CINCINNATI, OH 45202

EXAMINER
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ARNOLD, ERNST V

ART UNIT	PAPER NUMBER
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1613

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10/26/2011

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/803,126	<b>Applicant(s)</b> SCHWARTZ ET AL.	
	<b>Examiner</b> ERNST ARNOLD	<b>Art Unit</b> 1613	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 03 October 2011.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on \_\_\_\_; the restriction requirement and election have been incorporated into this action.
- 4) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 5) ☒ Claim(s) 1-3, 8, 11, 12, 14, 15 and 17-28 is/are pending in the application.
- 5a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 6) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 7) ☒ Claim(s) 1-3, 8, 11, 12, 14, 15, and 17-28 is/are rejected.
- 8) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 9) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 10) ☐ The specification is objected to by the Examiner.
- 11) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 12) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____.                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date ____.  | 6) <input type="checkbox"/> Other: ____.                          |

## DETAILED ACTION

Claims 1-3, 8, 11, 12, 14, 15 and 17-28 are pending and under examination.

### **Withdrawn rejections:**

Applicant's declaration, amendments and arguments filed 10/3/11 are acknowledged and have been fully considered. Any rejection and/or objection not specifically addressed below is herein withdrawn.

The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set of rejections and/or objections presently being applied to the instant application.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

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4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-3, 8, 11, 12, 14, 15, and 17-28 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Bhat et al. (WO 96/25913) in view of Gavin et al. (WO 01/00151).

Applicant claims:

- 1) (previously presented) A composition comprising:
  - a) from about 0.01 weight% to about 5 weight%, based on the total weight of the composition, of pyrithione or a polyvalent metal salt of a pyrithione, wherein the pyrithione or polyvalent metal salt of pyrithione is zinc pyrithione;
  - b) from about 0.001 weight% to about 10 weight%, based on the total weight of the composition, of a zinc-containing layered material which provides an augmentation factor greater than 1 wherein the zinc-containing layered material comprises an impurity containing hydroxy-containing basic zinc carbonate and further wherein the ratio of zinc-containing layered material to said pyrithione or a polyvalent metal salt of pyrithione is from about 1:2 to about 3:1.

### Determination of the scope and content of the prior art

#### (MPEP 2141.01)

Bhat et al. teach compositions comprising monophasic zinc hydroxycarbonate as antimicrobial agent in **personal care products**, such as shampoos, wherein there is a *synergistic action* of **zinc hydroxycarbonate** with detergent and/or anti-**dandruff** actives like **zinc pyrithione** in shampoos/hair dressings (pg. 8, lines 1-18 and claims 1-5 and 7). Thus, the art has already established compositions comprising zinc

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hydroxycarbonate and zinc pyrrhione in personal care products. Bhat et al. further teach personal care product compositions comprising a surfactant and monophasic zinc hydroxycarbonate in an amount of **0.1-20 wt.%** (Claims 1 and 2), wherein the structure of the zinc compound is  $Zn_5(OH)_6(CO_3)_2 \cdot X H_2O$ , where X varies between 0 and 4 (pg. 6, lines 23-27). When X=0 the same formula for **basic zinc carbonate**, a zinc-containing layered material, as disclosed by Applicants is taught (instant specification pg. 5, lines 16-20), which would intrinsically possess the same **augmentation factor greater than 1** as instantly claimed. From pages 1-2:

35 Basic zinc carbonate may be represented by




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and sometimes it is accompanied with ZnO.

The monophasic zinc hydroxycarbonate of the present invention has the following formula

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Since Applicant claims the zinc hydroxy carbonate when X = 0 (see instant claim 8), then any additional water represents an impurity to the 'pure' composition. The Examiner notes that 'impurities' are not defined in the specification as filed and that in

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[0033] of the USPGPUB it only teaches that other impurities may be incorporated in the crystal lattice. Therefore, water is interpreted as an impurity. Bhat et al. a method of making a composition by adding zinc hydroxycarbonate to a mixture (pg. 12, lines 1-31).

Bhat et al. teach various methods of making the basic zinc carbonate such as on page 5-6 and claim 6:

25 The process of the present invention for the preparation of zinc hydroxycarbonate, (suitable for use as antimicrobial agent in personal care compositions such as soaps, cosmetic - skin and hair- and dental formulations) comprises

30 (i) dissolving a soluble zinc salt in water and heating it, to keep the solution warm before use,

(ii) dissolving an alkali metal carbonate, such as sodium potassium or ammonium carbonate, in water,

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(iii) taking water in a precipitation vessel and maintaining it at 35-95 °C,

(iv) pumping warm solutions of (i) and (ii) into the precipitation vessel simultaneously, and maintaining the temperature at 50-98 °C with continuous stirring and warming if necessary,

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(v) filtering off the precipitate and washing it with water until it is free from anions, and

(vi) drying the washed material.

It is the Examiner's position that making this basic zinc carbonate intrinsically forms a layered film of an *in-situ* product reaction product because it is the same material as instantly claimed.

Gavin et al. disclose a topical anti-dandruff composition for treating microbes comprising from **0.001 to 10% zinc pyrithione**; from **0.001 to about 10% of a zinc salt** and an anionic deterative surfactant for a topical carrier (Claim 1). Thus if 10% zinc salt is present and 1% zinc pyrithione then a ratio of 10:1 is obtained or 10% zinc salt and 3.3% zinc pyrithione for a ratio of about 3:1 or there can be 5% of zinc salt and 10% of zinc pyrithione for a ratio of about 1:2. Gavin et al. disclose aqueous antimicrobial shampoo compositions containing zinc salt and zinc pyrithione and claim a shampoo composition comprising mixtures of zinc carbonate, zinc oxide, zinc hydroxide, cuprous ammonium carbonate, etc... (See examples 3-13 page 57-58 and claim 6). **Methods pertaining to treating microbial infections** preferably related to **dandruff** and treating athlete's foot, a contagious **fungal infection** (Claim 9).

#### **Ascertainment of the difference between the prior art and the claims**

##### **(MPEP 2141.02)**

1. The difference between the instant application and Bhat et al. is that Bhat et al. do not expressly teach the amount of zinc pyrithione present; the various 'augmentation factors'; or gallery ions in the zinc-containing layered material. This deficiency in Bhat et al. is cured by the teachings of Gavin et al.

2. The difference between the instant application and Bhat et al. is that Bhat et al. do not expressly teach a method for preparing a personal care composition by reacting in a personal care composition comprising zinc pyrithione a carbonate or bicarbonate with a zinc compound; wherein the molar ratio is between about 1:10 and about 10:1; and wherein the zinc pyrithione and the basic zinc carbonate are simultaneously or step wise generated. This deficiency in Bhat et al. is cured by the teachings of Gavin et al.

3. The difference between the instant application and Bhat et al. is that Bhat et al. do not expressly teach a method of treating microbial infections or fungal infections. This deficiency in Bhat et al. is cured by the teachings of Gavin et al.

### **Finding of prima facie obviousness**

#### **Rational and Motivation (MPEP 2142-2143)**

1. It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to make the composition of Bhat et al. with the amount of zinc pyrithione as suggested by Gavin et al., and produce the instant invention.

One of ordinary skill in the art would have been motivated to do this because Bhat et al. already teach adding zinc pyrithione and Gavin et al provide guidance as to how much to add. The 'augmentation factors' and presence of gallery ions are intrinsic to the composition since the same materials are used by Applicant.

2. It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to make the composition of Bhat et al. with the amount of



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zinc pyrithione as suggested by Gavin et al. by reacting in a personal care composition comprising zinc pyrithione a carbonate or bicarbonate with a zinc compound; wherein the molar ratio is between about 1:10 and about 10:1; and wherein the zinc pyrithione and the basic zinc carbonate are simultaneously or step wise generated, and produce the instant invention.

One of ordinary skill in the art would have been motivated to do this because it is merely judicious selection of steps to combine the ingredients by one of ordinary skill in the art. With regard to the amount of carbonate or bicarbonate to add to make the instantly claimed ratios, it is the Examiner's position that the amount of a specific ingredient in a composition is clearly a result effective parameter that a person of ordinary skill in the art would routinely optimize. Optimization of parameters is a routine practice that would be obvious for a person of ordinary skill in the art to employ. It would have been customary for an artisan of ordinary skill to determine the optimal amount of each ingredient needed to achieve the desired results. Thus, absent some demonstration of unexpected results from the claimed parameters, the optimization of ingredient amounts would have been obvious at the time of applicant's invention. Bhat et al. already teach how to make the basic zinc carbonate and it is merely a design choice to make it *in situ*; step wise or simultaneously in the absence of evidence to the contrary.

3. It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to use the composition of Bhat et al. in a method of treating

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microbial infections or fungal infections as suggested by Gavin et al., and produce the instant invention.

One of ordinary skill in the art would have been motivated to do this because Gavin et al. suggest these uses for the composition.

In light of the forgoing discussion, the Examiner concludes that the subject matter defined by the instant claims would have been obvious within the meaning of 35 USC 103(a).

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

**Response to arguments:**

Applicant asserts that x-ray diffraction, as provided above, requires a crystal structure and thus a solid and that water is not a solid and would not provide the x-ray diffraction impurities provided by the Declaration of May 25, 2010. Applicant then asserts that water would need to be in the form of a solid, such as ice, in order to be measured in an x-ray diffraction. Applicant concludes that water cannot be an impurity. Respectfully, the Examiner cannot agree for the following reasons.

1. Water is routinely crystallized with other crystal lattices and hydrated x-ray crystal structures are well known in the art and is known in crystallography as water of crystallization or water of hydration. (Water of Crystallization Merriam-Webster's

online dictionary). Consequently, the Examiner is not persuaded by Applicant's argument.

2. The identity of the impurity is not identified in the claims and it is improper to read limitations from the specification into the claims. From MPEP 2173.05(r): *In re Winkhaus*, 527 F.2d 637, 188 USPQ 129 (CCPA 1975), which discuss the premise that one cannot rely on the specification to impart limitations to the claim that are not recited in the claim.
3. Even if Applicant were to define impurities as something other than water, then the Examiner's position would not be changed because an impurity is simply a foreign substance present at a low concentration in another substance and nothing has been shown about the criticality of having an unknown low if not negligible amount of an unknown impurity in the composition.

Applicant asserts that there is no basis for suggesting that an impurity of any kind can be included in the zinc hydroxycarbonate disclosed in Bhat. Respectfully, the Examiner cannot agree because Bhat teaches additional waters can be present in the composition.

Applicant asserts that the 1.132 Declaration filed on 2/17/11 presents data indicating a strong correlation between zinc lability and the ability of a material to release zinc ions, which are the source of the augmentation benefit. Applicant asserts that the basic zinc carbonate without other impurity phases or monophasic, such as those from monophasic Elementis and Cater, representative of the monophasic material

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of Bhat, do not possess the same efficacy as an impurity containing basic zinc carbonate such as Bruggemann. The proper data from the Declaration is this:

Source of Material	Relative Zinc Lability (%)
Bruggemann	56.9
Cater	42.3
Elementis	51.6

There is no standard deviation and it appears that all three sources of material have the same degree of relative zinc lability, especially Bruggemann and monophasic Elementis. This is also reflected in comparable reductions in *Malassezia* counts where Bruggemann had 251.2 and Elementis had 214.1 which appears to be only a slight difference in degree; not a difference in kind.

Applicant asserts that there is no supporting data in Bhat that would suggest the augmenting effect of basic zinc carbonate on ZPT for in vivo *Malassezia* reduction capability. The Examiner has these remarks to this assertion:

1. As discussed above, Bhat clearly teaches that there is a *synergistic action* of **zinc hydroxycarbonate** with detergent and/or anti-**dandruff** actives like **zinc pyrithione** in shampoos/hair dressings.
2. Bhat clearly states that zinc hydroxycarbonate releases zinc ions acting on the skin microflora (page 8, lines 13-16) thus acknowledging that these compounds have a 'relative zinc lability' and hence any augmentation factor that comes with the zinc lability. In addition, the zinc

hydroxycarbonate is available commercially as taught by Applicant in [0032] and available to the ordinary artisan. Essentially, it comes down to judicious selection of known sources of zinc hydroxycarbonate for use in the composition and methods. Applicant has not shown synergistic effects due to the composition per se but only the effects of known commercial products. This is not inventive given the teachings of Bhat because Bhat teach the ordinary artisan to select zinc hydroxycarbonate and that the release of zinc ions is what acts on the microflora and consequently Applicant's declaration data is an expected result. In other words, it is expected that the more zinc released then the better the effect. The ordinary artisan would desire the highest release of zinc ions to obtain the maximum effect. Therefore, selection of the commercially available Bruggemann or monophasic Elementis sample is an obvious choice to the ordinary artisan. Respectfully, patentability is determined on the totality of the record, by a preponderance of evidence with due consideration to persuasiveness of argument and the present declaration and arguments are not persuasive to overcome the rejection for the reasons discussed above.

Applicant asserts that it was undue experimentation that led to the present invention. This argument is not persuasive as there are a limited number of sources of basic zinc carbonate and Bhat already discloses synergistic action in combination with

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ZPT. In an alternative interpretation of the art, the composition of Bhat is open to the addition of other elements which include other phases of basic zinc carbonate.

At the heart of the disagreement between Applicant and the Examiner is the chemical identity of the instantly claimed basic zinc carbonate with its impurity. It is the Examiner's position that Applicant has not sufficiently described the impurity containing basic zinc carbonate in clear and unambiguous terms and that the impurity containing basic zinc carbonate is really no different from the at least the monophasic Elementis material, which, however, Applicant states is different. Respectfully, the Examiner cannot agree because the two materials have similar, if not the same, activity as shown in Applicant's data. From MPEP 2163: *Amgen, Inc. v. Chugai Pharmaceutical Co., Ltd.*, 927 F.2d 1200, 1206, 18 USPQ2d 1016, 1021 (Fed. Cir. 1991) ("it is well established in our law that conception of a chemical compound requires that the inventor be able to define it so as to distinguish it from other materials, and to describe how to obtain it").

*Objective evidence of a true side by side comparison with the composition of Bhat demonstrating a superior property of the instantly claimed composition has not been shown for the Examiner to consider non-obviousness.*

Applicant asserts that there is not teaching in Bhat in view of Gavin that would lead one of skill in the art to further find a strong correlation between zinc lability and product efficacy, as expected from the mechanistic understanding: zinc lability is a measure of the ability of a material to release zinc ions, which are the source of the augmentation benefit. Respectfully, the Examiner cannot agree. Clearly Bhat teaches:

*"It is known that divalent zinc ions can provide antimicrobial activity. If they are made available freely in soaps or cosmetic or dental formulations, they would contribute to the health care features of these products."* (page 2, lines 8-11).

*"...zinc hydroxycarbonate, not being soluble in water,... delivers zinc ions which act on microbes..."* (page 2, lines 29-34).

*"Thus, zinc hydroxycarbonate acts as an agent to generate active antibacterial/antimicrobial species – zinc ions – by its synergistic combinations with surfactants such as soaps/synthetic detergents."* (page 3, lines 4-8). **Clearly, Bhat had a mechanistic understanding between zinc lability and product efficacy as Bhat was aware of the benefit of the release of zinc ions from zinc hydroxycarbonate and its benefit.** Arguments to the contrary are simply not based on the facts in the art.

Pages 13 and 14 of the instant remarks appear to be cut and paste verbatim arguments presented previously. As such, the Examiner reply to these arguments is relied upon again here.

***Conclusion***

No claims are allowed.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ERNST ARNOLD whose telephone number is (571)272-8509. The examiner can normally be reached on M-F 7:15-4:45.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Kwon can be reached on 571-272-0581. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.



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/Ernst V Arnold/  
Primary Examiner, Art Unit 1613